

4389 FIRST AID KIT- 4389 first aid kit

Honeywell Safety Products USA, INC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

4389 First Aid Kit (Burn Jel, BZK wipes, EW, aypanal, triple, Cedaprin, ASA, amm. Inh - 68P24AG)

Eyewash

Active ingredient

Sterile Water 99%

Eyewash

Purpose

Eyewash

Eyewash

Uses

- for flushing the eye to remove loose foreign material, air pollutants or chlorinated water

Eyewash

Warnings

For external use only Obtain immediate medical treatment for all open wounds in or near eyes. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard.

Do not use

- if solution changes color or becomes cloudy
- if you have open wounds in or near the eyes, get medical help right away.

Stop use and ask a doctor if

- you experience eye pain
- changes in vision
- continued redness or irritation of the eye
- condition worsens or persists

Keep out of reach of children

- If swallowed, get medical help or contact a Poison Control Center right away.

Eyewash

Directions

- remove contacts before using
- twist top to remove
- flush the affected area as needed
- control rate of flow by pressure on the bottle
- if necessary, continue flushing with emergency eyewash or shower

Eyewash

Inactive ingredients

sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic

Eyewash

Questions

1-800-430-5490

Aspirin

Active ingredient (in each tablet)

Aspirin 325 mg (NSAID)* *nonsteroidal anti-inflammatory drug

Aspirin

Purpose

Pain reliever/fever reducer

Aspirin

Uses

temporarily reduces fever and relieves minor aches and pains associated with:

- a cold
- headache
- toothache
- muscular aches
- backache
- minor pain of arthritis
- premenstrual and menstrual periods

Aspirin

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:are:

- age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Do not use

- if you are allergic to aspirin or any other pain reliever/fever reducer

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for diabetes, gout or arthritis

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- ringing in the ears or loss of hearing occurs
- any new symptoms appear

If pregnant or breast-feeding,

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last three months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

- In case of overdose, get medical help or contact Poison Control Center right away.

Aspirin***Directions***

- drink a full glass of water with each dose
- adults and children 12 years of age and older: take 1 or 2 tablets every 4 hours while symptoms last, not more than 12 tablets in 24 hours
- children under 12 years of age: consult a doctor

Aspirin***Other information***

- store at room temperature 15° - 30°C (59° - 86°F)
- TAMPER EVIDENT PACKETS
- DO NOT USE IF OPEN OR TORN

Aspirin***Inactive ingredients***

corn starch, croscarmellose sodium*, hypromellose*, microcrystalline cellulose*, mineral oil*, polyethylene glycol*, povidone, propylene glycol, silicon dioxide, stearic acid*, titanium dioxide*

*may contain these ingredients

Aspirin***Questions or Comments***

1-800-430-5490

Ammonia***Active ingredient***

Ammonia 15%

Ammonia***Purpose***

Respiratory stimulant

Ammonia***Uses***

- to prevent or treat fainting

Ammonia***Warnings***

For external use only

Do not use

- if you have breathing problems such as asthma or emphysema

Stop use and ask a doctor if

- condition persists

Keep out of reach of children

- If swallowed get medical help or contact a Poison Control Center right away.

Ammonia***Directions***

- hold inhalant away from face and crush ampoule between thumb and forefinger at position indicated on sleeve.
- hold near nostrils for inhalation of volatile vapor

Ammonia***Other information***

- store at room temperature away from light

Ammonia***Inactive ingredient***

alcohol USP, FD&C red #40, lavender oil, lemon oil fcc, nutmeg oil, purified water

Ammonia***Questions or Comments?***

1-800-430-5490

BZK***Active ingredient***

Benzalkonium chloride 0.13% w/v

BZK***Purpose***

First aid antiseptic

BZK***Uses***

Antiseptic cleansing of face, hands, and body without soap and water

BZK***Warnings*****For external use only****Do not use**

- in the eyes or over large areas of the body
- on mucous membranes
- on irritated skin
- in case of deep puncture wounds, animal bites or serious burns, consult a doctor
- longer than 1 week unless directed by a doctor

Stop use and ask a doctor if

- if irritation, redness or other symptoms develop
- the condition persists or gets worse

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

BZK***Directions***

tear open packet and use as a washcloth

BZK

Other information

- store at room temperature 15⁰ to 30⁰ C (5⁰ - 86⁰ F)
- do not reuse towelette

BZK

Inactive ingredient

water

BzK

Questions

1-800-430-5490

Cedaprin

Active ingredient

Ibuprofen 200 mg (NSAID)

*(nonsteroidal anti-inflammatory drug)

Cedaprin

Purpose

Pain reliever/fever reducer

Cedaprin

Uses

temporarily relieves minor aches and pains due to:

- headache
- muscular aches
- minor pain of arthritis
- toothache
- backache
- the common cold
- menstrual cramps
- temporarily reduces fever

Cedaprin

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include:

- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

-

If an allergic reaction occurs, stop use and seek medical help right away.

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning:

- NSAID's, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

Do not use

- if you have ever had an allergic reaction to ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- you have problems or serious side effects from taking pain relievers or fever reducers
- stomach bleeding warning applies to you
- you have a history of stomach problems such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma or had a stroke
- you are taking a diuretic

Ask a doctor or a pharmacist before use if you are

- taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin
- under a doctors care for any serious condition
- taking any other drug

When using this product,

take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing
 - weakness in one part or side of body
 - slurred speech
 - leg swelling

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away(1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Cedaprin

Directions

- do not take more than directed
- the smallest effective dose should be used
- adult and children 12 years of age and over:
- take 1 tablet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 tablet, 2 tablets may be used
- do not exceed 6 tablets in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

Cedaprin

Other information

- store between 15 ° -30 ° C (59 ° -86 ° F)
- avoid excessive heat and humidity
- TAMPER EVIDENT PACKETS- DO NOT USE IF OPEN OR TORN

Cedaprin

Inactive ingredients

hypromellose, lactose monohydrate, opadry II 31K, povidone K-30, ferric oxide red, silicon dioxide, starch, stearic acid, titanium dioxide, triacetin

Questions or Comments?

1-800-430-590

Burn Jel

Active ingredient

Lidocaine HCl 2.0 %

Burn Jel

Purpose

External analgesic

Burn Jel***Uses***

temporarily relieves pain due to minor burns

Burn Jel***Warnings***

For external use only

Do not use

- on large areas of the body, particularly over raw surfaces or blistered areas

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- the condition gets worse
- symptoms persist for more than 7 days
- condition clears up and recurs within a few days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Burn Jel***Directions***

- adults and children 2 years of age and older; apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor
- you may report a serious reaction to this product to 800-430-5490

Burn Jel***Other information***

- store at room temperature
- do not use if opened or torn

Burn Jel***Inactive ingredients***

carbopol 940, carbopol 1342, diazolidinyl urea, glycerin, melaleuca alternifolia (tea tree) leaf oil, methylparaben, octoxynol-9, propylene glycol, propylparaben, trolamine, water ...

Burn Jel***Questions***

1-800-430-5490

Triple***Active ingredients***

Bacitracin zinc 400 units

Neomycin sulfate (5 mg equivalent to 3.5 mg Neomycin base)

Polymyxin B sulfate 5000 units

Triple

Purpose

First aid antibiotic

First aid antibiotic

First aid antibiotic

Triple

Uses

- first aid to help prevent infection in
- minor cuts
- scrapes
- burns

Triple

Warnings

For external use only

Allergy alert do not use if you are allergic to any of the ingredients

Do not use

in the eyes

over large areas of the body

Ask a doctor before use if you have

- a deep or puncture wounds
 - animal bites
 - serious burns
- do not use if you are allergic to any of the ingredients

Stop use and ask a doctor if

- the condition persists or gets worse
- a rash or other allergic reaction develops
- you need to use longer than 1 week

Keep out of the reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

Triple

Directions

- clean the affected area
- apply a small amount of the product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily
- may be covered with a sterile bandage

Triple

Other information

- store at 15⁰ to 25⁰ C (59⁰ to 77⁰ F)
- tamper evident sealed packets
- do not use if packet is torn or opened

Triple

Inactive ingredient

petrolatum

Triple

Questions?

1-800-430-5490

Aypanal

Active ingredient (in each tablet)

Acetaminophen 500 mg

Aypanal Ex

Purpose

Pain reliever/fever reducer

Aypanal Ex

Uses

- temporarily relieves minor aches and pains due to the common cold and headache
- temporarily reduces fever

Aypanal Ex

Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg in 24 hours, which is the maximum daily amount.
- with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If skin reaction occurs, stop use and seek medical help right away

Do Not Use

with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

liver disease

Ask a doctor or pharmacist before use if

you are taking the blood thinning drug warfarin

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

If pregnant or breastfeeding,

ask a health professional before use.

Keep out of reach of children.

Overdose warning: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Aypanal Ex***Directions***

- do not take more than directed (see overdose warning)
- adults and children 12 years of age and over: Take 2 tablets with water every 6 hours while symptoms last.
- do not take any more than 8 tablets in 24 hours.
- children under 12: consult a doctor

Aypanal Ex***Other information***

- Store at room temperature 15°-30° C (59°-86° F)
- TAMPER EVIDENT- DO NOT USE IF OPEN OR TORN

Aypanal Ex***Inactive ingredients***

microcrystalline cellulose, povidone, sodium starch glycolate, starch, stearic acid

Aypanal Ex***Questions or Comments?***

1-800-430-5490

4389

68P24AG KIT CONTENTS

1 TRIANGULAR BDG, NON-STERILE
3 INSTANT COLD PACK 4" X 6"
1 ADHESIVE BDG, PLSTIC, 1"X3" 16PER
1 BURN JEL 1/8 OZ, 6 PER
1 NITRILE GLOVES 2PR BBP
1 ANTIMICRBL ANTSPCTC TWLETTTS
1 ELASTIC BANDAGE 3" X 4.5YD
1 CPR FILTERSHIELD 77-100
1 4OZ BFS EYEWASH TRILINGUAL BOTTLE
1 SCISSOR BDGE 4" RED PLS HDL
1 KIT TWEEZER 3 1/2" SLANTED
1 BANDAGE COMP 4" W/TELFA PAD 1
LBL STOCK 6-3/8"X4"
LBL STOCK 4"X2-7/8"
1 LBL STOCK 3"x1-7/8"
1 TRIPLE BIOTIC 12 PER ZIP BAG
1 CEDAPRIN 12 PACK PER ZIP BAG
1 aspirin 12 PACK PER ZIP BAG
1 KIT PP 24 UNIT FA
1 ADHS TAPE .5"X2.5YD 2
1 GAUZE PADS 3"X3" 4/BX
3 AMMONIA INHALANT, BULK

Eyewash

Principal Display Panel

Honeywell

TAMPER-EVIDENT CAP.
TAPA CON SELLO DE SEGURIDAD.
BOUCHON INDICATEUR D'INFRACTION.

eyesaline®

LAVAOJOS
EYESALINE

Solución
Isotónico Estéril

EYESALINE
EYEWASH

Sterile
Isotonic Solution

LAVAGE
OCULAIRE
EYESALINE

La Solution
Isotonique Stérile

16 fl. oz. (473 mL)

NPN: 80057528



Drug Facts (for USA only)

Active ingredient	Purpose
Sterile water 99%	Eyewash
Uses for flushing the eye to remove loose foreign material, air pollutants, or chlorinated water.	
Warnings For external use only - Obtain immediate medical treatment for all open wounds in or near the eyes. To avoid contamination, do not touch tip of container to any surface. Do not reuse. Once opened, discard. Do not use • if solution changes color or becomes cloudy • if you have open wounds in or near the eyes, get medical help right away Stop use and consult a doctor if: • you experience eye pain • changes in vision • continued redness or irritation of the eye • condition worsens or persists Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
Directions • remove contacts before using • twist top to remove • flush the affected area as needed • control rate of flow by pressure on the bottle • if necessary, continue flushing with emergency eyewash or shower	
Inactive ingredients sodium chloride, sodium phosphate dibasic, sodium phosphate monobasic	
Questions? Call 1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI. 02917	

LABEL 432-004510 Rev. J REORDER / NUEVO PEDIDO / RÉAPPROVISIONNEMENT 432-000454-0000

space for lot code and supplier part number

PEEL / PELAR / PELER

Datos de medicamento (Para EE.UU. solamente)

Ingrediente Activo	Propósito
Agua estéril 99%	Lavaojos
Usos para el lavado de ojo para quitar las partículas sueltas y extrañas, los contaminantes aeros, o agua de cloruro.	
Advertencias Para el uso externo sólo - Obtenga tratamiento médico inmediato para todas las heridas abiertas en o cerca de los ojos. Para evitar la contaminación, no toque la punta del envase con ninguna superficie. No vuelva a usar. Vez abierto, descarte. No se use • si la solución se enturbia o cambia de color • si tiene heridas abiertas en o cerca del ojo, obtenga ayuda médica de inmediato Deje de usar y consulte a un médico si: • experimenta dolor de ojo • cambio de visión • rojez continuo o irritación del ojo • la condición empeora o persiste Manténgase fuera del alcance de los niños. En caso de ingestión accidental, obtenga atención médica o llame a un Centro de control de envenenamiento inmediatamente.	
Instrucciones • quítense los lentes de contacto antes de usar la solución • tuerza la tapa para quitar • enjuague el área afectada según se necesite • controle el chorro haciendo presión en la botella • si es necesario, sigue enjuagado con un lavaojos o ducha de emergencia	
Ingredientes inactivos cloruro de sodio, fosfato de sodio dibásico, fosfato de sodio monobásico	
¿Preguntas? Llame al 1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI. 02917	

Information

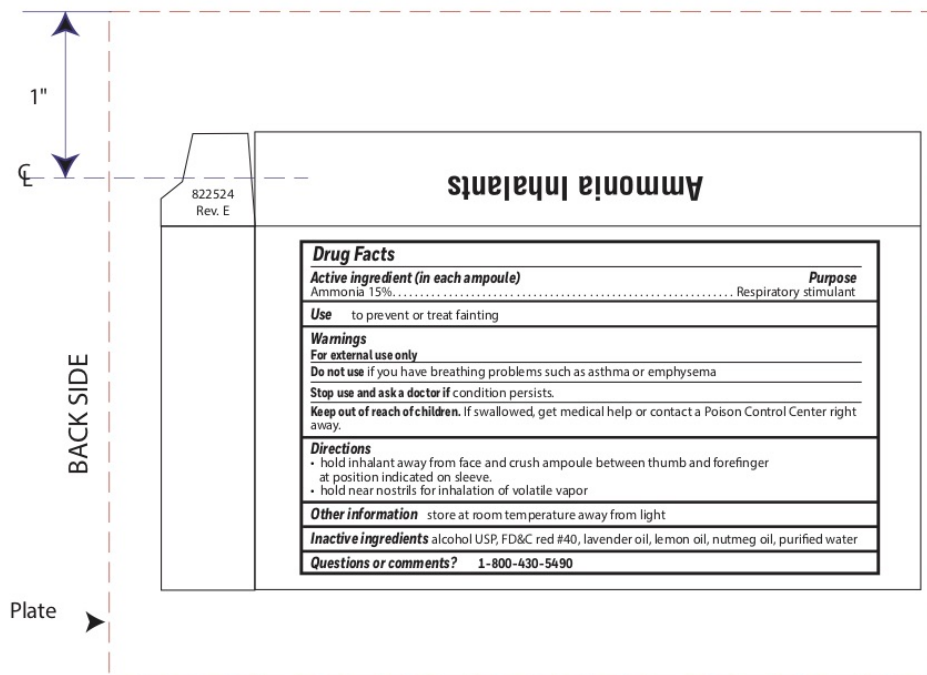
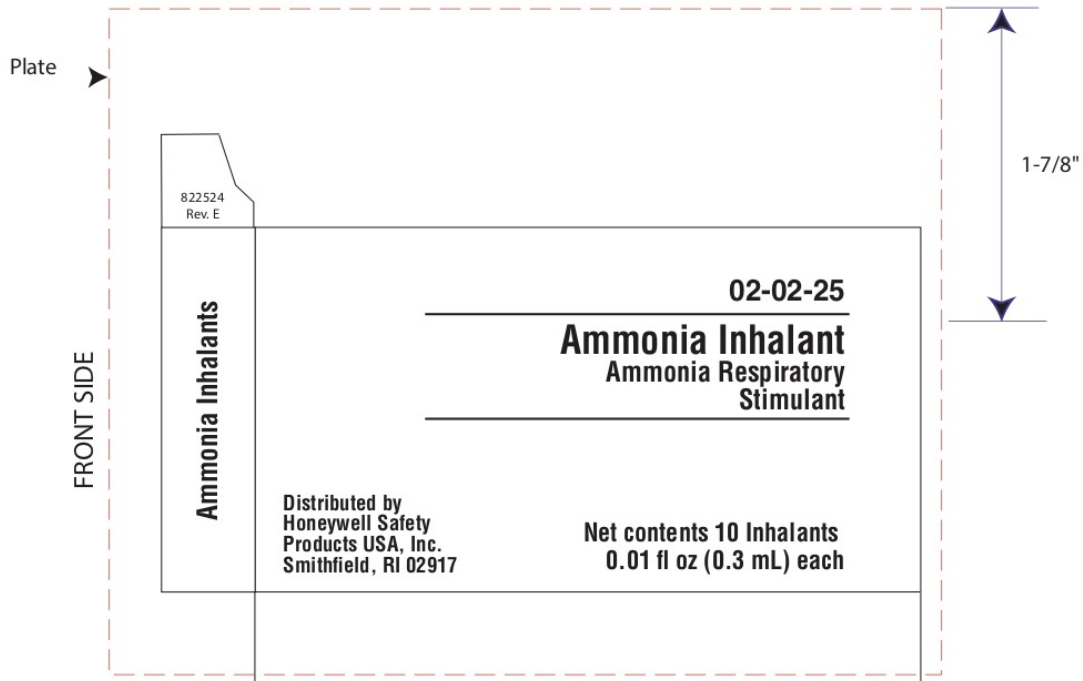
Usages Pour le rinçage des yeux afin d'enlever un corps étranger, des polluants atmosphériques ou de l'eau chlorée.
Advertissements Pour usage externe seulement - Obtenir immédiatement des soins médicaux pour toutes les plaies ouvertes dans ou près des yeux. Pour éviter toute contamination, ne pas toucher la pointe du récipient à n'importe quelle surface. Ne pas réutiliser. Une fois ouvert, jetez-le. Ne pas utiliser • si la solution a changé de couleur ou si elle est brouillée • si vous avez des plaies ouvertes aux yeux ou à proximité, consultez immédiatement un médecin Cesser d'utiliser la solution et consulter un médecin • vous ressentez une douleur oculaire • si votre vision change • rougeur ou irritation persistante des yeux • condition empire ou persiste Garder hors de la portée des enfants. En cas d'ingestion, communiquer immédiatement avec un médecin ou avec un centre antipoison.
Mode d'emploi • enlever les verres de contact avant l'utilisation • dévisser le bouchon pour l'enlever • rincer la zone touchée selon les besoins • ajuster le débit d'écoulement de la solution en augmentant ou en réduisant la pression exercée sur le contenant • si nécessaire, continuer de rincer avec une solution de rinçage oculaire d'urgence ou une douche
Ingédients eau stérile, chlorure de sodium, phosphate dibasique de sodium, phosphate monobasique de sodium
Des questions? Faites le 1-800-430-5490 Honeywell Safety Products USA, Inc. Smithfield, RI. 02917

Aspirin
Principal Display Panel

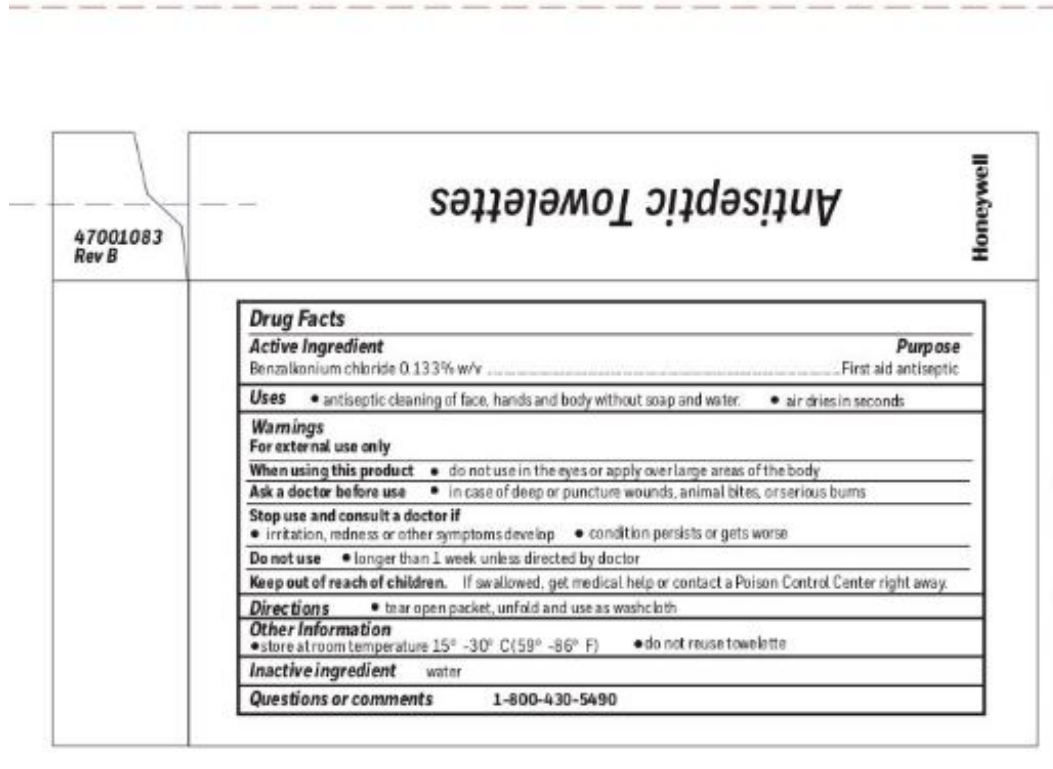
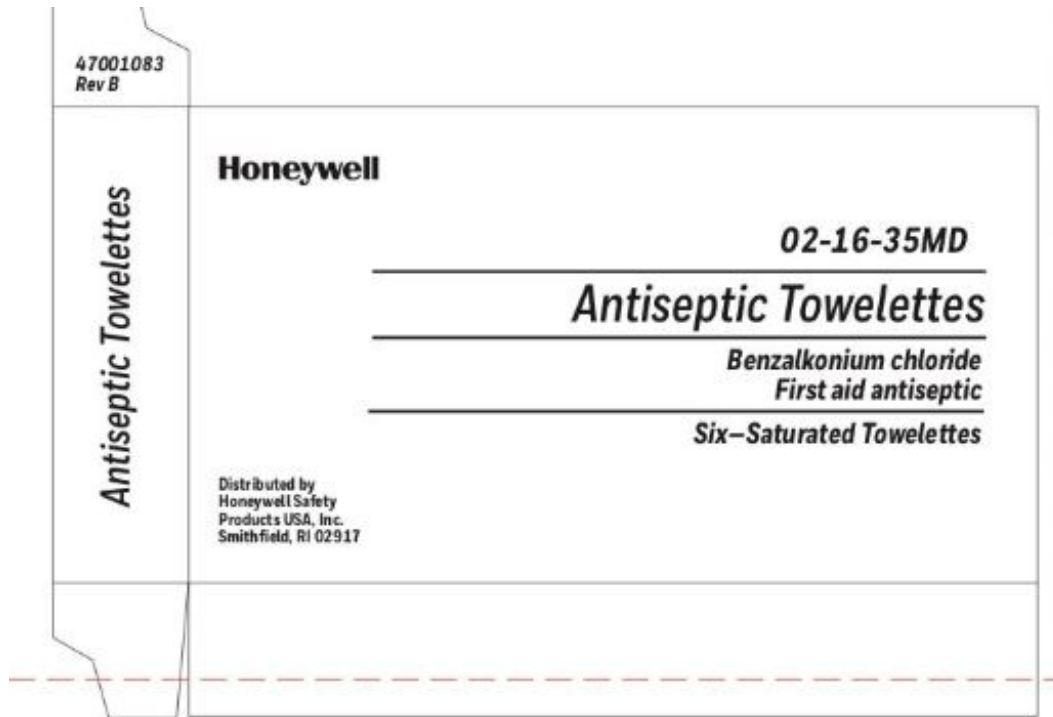


Ammonia
Principal Display Panel

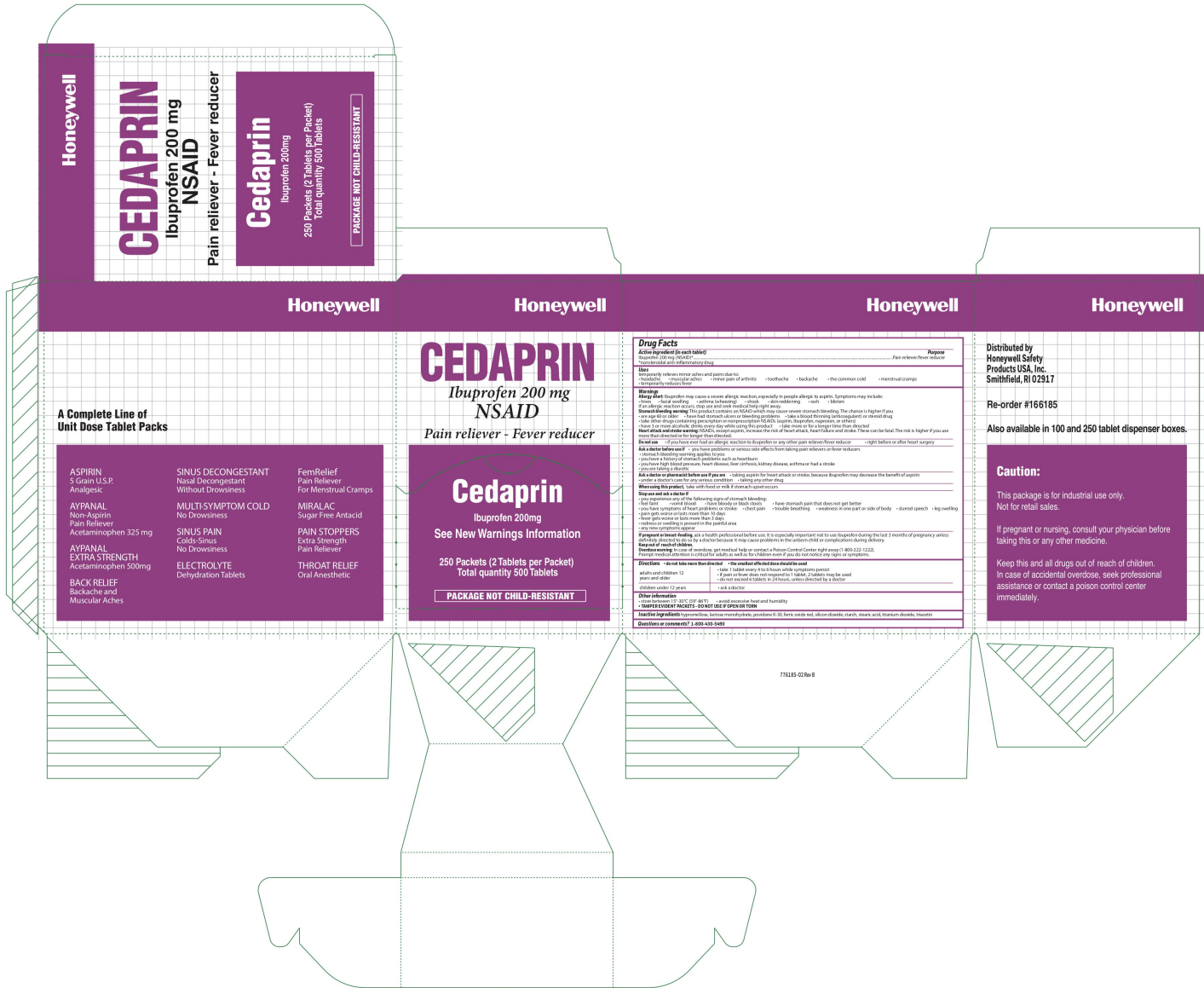
796006 Rev. E Unit Carton Printing Plate for "A" size carton.



Principal Display Panel



Cedaprin Principal Display Panel



Burn Jel
Principal Display Panel

02-10-20

Burn Jel®
Lidocaine HCl 2%
External Analgesic

6 Packets, Net Wt 1/8 oz (3.5 g) each

Distributed by
Honeywell Safety
Products USA, Inc.
Smithfield, RI 02917

PACKAGE NOT CHILD-RESISTANT

ANSI Z308.1-2003

Burn Jel®

Drug Facts

Active ingredient	Purpose
Lidocaine HCl 2%	External analgesic

Uses temporarily relieves pain due to minor burns

Warnings

For external use only

Do not use over large areas of the body, particularly over raw surfaces or blistered areas

When using this product avoid contact with eyes

Stop use and ask a doctor if

- the condition gets worse
- symptoms persist for more than 7 days
- condition clears up and recurs within a few days

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

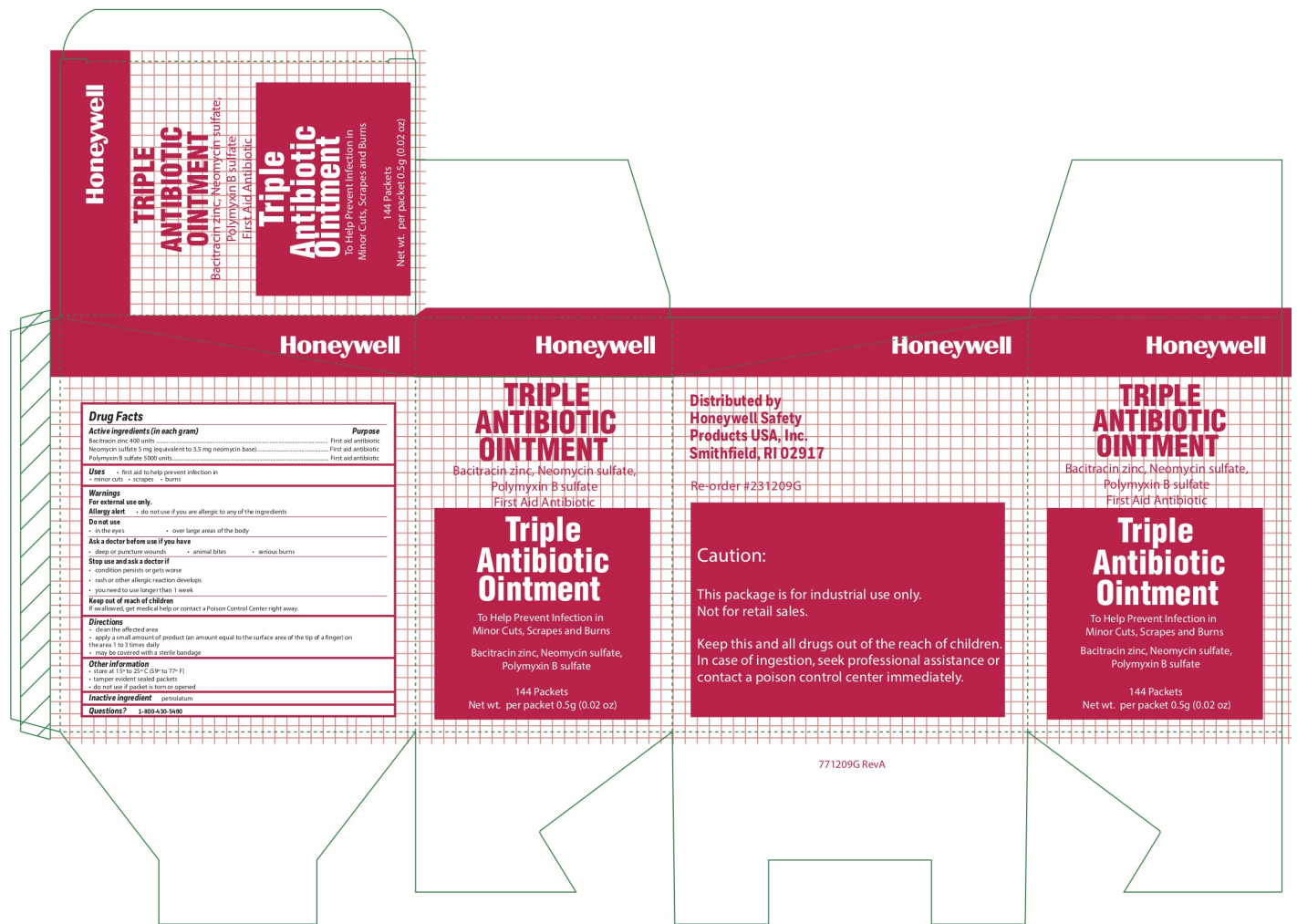
- adults and children 2 years of age and older: apply to affected area not more than 3 - 4 times daily
- children under 2 years of age: ask a doctor
- you may report a serious adverse reaction to this product to 800-430-5490

Other information • store at room temperature 15 - 30°C (59-86°F) • do not use torn or open

Inactive ingredient carbopol 940, carbopol 1342, diazolidinyl urea, glycerin, melaleuca alternifolia (tea tree) leaf oil, methylparaben, octoxynol-9, propylene glycol, propylparaben, triethylamine, water

Questions or comments? 1-800-430-5490

Triple
Principal Display Panel



Aypanal EX
Principal Display Panel



Distributed by Honeywell Safety Products USA, Inc Smithfield, RI 02917

4389 FIRST AID KIT

4389 first aid kit kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0498-4389
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4389-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	118 mL
Part 2	12 PACKET	24
Part 3	3 AMPULE	0.9 mL
Part 4	1 PACKET	1.4 mL
Part 5	12 PACKET	24
Part 6	12 PACKET	24
Part 7	12 PACKET	10.8 g
Part 8	6 PACKET	21 g

Part 1 of 8

EYESALINE EMERGENCY EYEWASH

purified water liquid

Product Information

Item Code (Source)	NDC:0498-0100
Route of Administration	OPHTHALMIC

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WATER (UNII: 059QF0KO0R) (WATER - UNII:059QF0KO0R)	WATER	98.6 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM PHOSPHATE, DIBASIC (UNII: GR686LBA74)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0100-02	118 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	12/18/2018	

Part 2 of 8

ASPIRIN

aspirin tablet

Product Information

Item Code (Source)	NDC:0498-0114
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	325 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
MINERAL OIL (UNII: T5L8T28FGP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	10mm
Flavor		Imprint Code	FR21
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0114-01	2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	09/18/2018	

Part 3 of 8

AMMONIA INHALENT

ammonia inhalent inhalant

Product Information

Item Code (Source)	NDC:0498-3334
Route of Administration	RESPIRATORY (INHALATION)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMMONIA (UNII: 5138Q19F1X) (AMMONIA - UNII:5138Q19F1X)	AMMONIA	0.045 g in 0.3 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-3334-00	0.3 mL in 1 AMPULE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/18/2018	

Part 4 of 8

ANTISEPTIC TOWELETTE

benzalkonium chloride liquid

Product Information

Item Code (Source)	NDC:0498-0501
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL
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Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0501-00	1.4 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	12/22/2017	

Part 5 of 8

AYPANAL EX

acetaminophen tablet

Product Information

Item Code (Source)	NDC:0498-2110
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics

Color	white	Score	no score
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Shape	ROUND	Size	12mm
Flavor		Imprint Code	FR1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-2110-01	2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/02/2017	

Part 6 of 8

CEDAPRIN

ibuprofen tablet

Product Information

Item Code (Source)	NDC:0498-7502
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TRIACETIN (UNII: XHX3C3X673)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	

Product Characteristics

Color	red	Score	no score
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Shape	ROUND	Size	10 mm
Flavor		Imprint Code	G;2
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-7502-01	2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079129	01/02/2017	

Part 7 of 8	
TRIPLE ANTIBIOTIC	
bacitracin zinc, polymyxin b sulfate, neomycin sulfate ointment	

Product Information	
Item Code (Source)	NDC:0498-0750
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name		Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)		400 [iU] in 1 g
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)		3.5 mg in 1 g
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)		5000 [iU] in 1 g

Inactive Ingredients	
Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging			
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#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0750-35	0.9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	09/19/2018	

Part 8 of 8

BURN JEL

gel for burns gel

Product Information

Item Code (Source)	NDC:0498-0203
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
OCTOXYNOL-9 (UNII: 7JPC6Y25QS)	
TROLAMINE (UNII: 9O3K93S3TK)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
DIPROPYLENE GLYCOL (UNII: E107L85C40)	
GLYCERIN (UNII: PDC6A3C0OX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TEA TREE OIL (UNII: VIF565UC2G)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0203-00	3.5 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/19/2018	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/18/2018	

Labeler - Honeywell Safety Products USA, INC (079287321)

Establishment			
Name	Address	ID/FEI	Business Operations
James Alexander		040756421	manufacture(0498-3334)

Establishment			
Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, INC		079287321	pack(0498-4389)

Establishment			
Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	manufacture(0498-0114, 0498-2110)

Establishment			
Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(0498-0203, 0498-0750)

Establishment			
Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, Inc.		167518617	manufacture(0498-0100)

Establishment			
Name	Address	ID/FEI	Business Operations
Changzhou Maokang Medical		421317073	manufacture(0498-0501)

Establishment			
Name	Address	ID/FEI	Business Operations
Granules of India Limited		918609236	manufacture(0498-7502)